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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,386	04/03/2002	Sharron Gaynor Penn	PB-01106	4235

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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/029,386	PENN ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/3/02* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-40, 44, drawn to nucleic acid probes for measuring human gene expression selected from SEQ ID NO:s: 13,701-27,400 and Tables 4-11 and vectors, classified in class 536, subclass 23.1, 435/320.1. This group is subject to further restriction.

II. Claims 41-43, drawn to a method of measuring human gene expression using a microarray, classified in class 435, subclass 6.

III. Claims 45-46, drawn to an ORF-encoded peptide, classified in class 530, subclass 300 or 350, for example.

IV. Claims 47, drawn to an antibody, classified in class 424, subclass 130.1.

V. Claims 48-49, drawn to a method of selling and/or licensing, classified in class 705, subclass 26.

VI. Claims 50, drawn to a method of providing human gene expression data by subscription by making database available, classified in class 707, subclass 3.

VII. Claims 51, 53, drawn to a computer readable storage medium, classified in class 707, subclass 100.

VIII. Claim 52, drawn to a computer system, classified in class 700, subclass 1.

Restriction Requirement Applicable to All Groups:

2. The instant claims are drawn to over 14,000 sequences identified by SEQ ID NO:. For example, Claim 1 sets forth a claim directed to SE QID NO:S 13,701-27,400. Each sequence is patentably distinct because they are unrelated sequences, i.e. these sequences are unrelated because the protein encoded by these sequences differ in structure and in function and in biological activity. The claims contains over 14,000 individual, independent and distinct nucleotide sequences in alternative form. Accordingly, these claims are subject to restriction under 35 U.S.C. 121 as outlined in 1192 O.G. 68 (November 19, 1996).

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

Applicant is required to select one of the individual sequences for examination. The search of the selected sequence may include the complements of the selected sequences and, where appropriate, may include subsequences within the selected sequences (e.g., oligomeric probes and/or primers). For an elected Group drawn to

nucleotide sequences, the Applicants are permitted to elect a single nucleic acid sequences (See MPEP 803.04).

Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evident or identify such evidence now of record showing the species to be obvious variant or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

For Claims 13-23 applicant is further required to select a single probe combination of second probes. Which are contiguous. Claim 15 requires SEQ ID NO:s 1-13,700. Moreover, in the event that the elected nucleic acid probe corresponds to an amino acid sequence of SEQ ID NO: 27,401-34,288, applicant is requested to indicate the corresponding amino acid sequence (Claim 28). Claims 29 are further directed to probe sets of between 50-20,000 probes. Applicant is requested to select a single combination of probes comprising the previously elected single nucleic acid elected from Claim 1. The combination may be any single combination within the scope of the claims. For example applicant may either select a combination comprising SEQ ID NO: 13,701 (for example) or a combination of 50 probes, namely SEQ ID NO: 13,701-13,750 (for example) or a combination of 20,000 probes.

3. The inventions are distinct, each from the other because of the following reasons:

A) The inventions are distinct, each from the other because of the following reasons: The inventions of Groups I, III, IV, VII and VIII are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of Group I is composed of nucleotides linked in phospodiester bonds and arranged in space as a double helix. The polypeptide of Group III is composed of amino acids linked in peptide bonds and arranged spatially in a number of different tertiary structures including alpha helices, beta-pleated sheets, and hydrophobic loops (transmembrane domain). The antibody of Group IV is also composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The computer readable medium of Group VII is composed of electronic hardware. The computer system is comprised of a output display, an input system and a processor. Furthermore, the products of Groups I, III, IV, VII and VIII can be used in materially different processes, for example, the DNA of Group I can be used in hybridization assays, the antibody of Group IV can be used in immunoassay, the polypeptide of Group III can be used to make fusion protein with an enzymatic function, while computer storage mediums may be used to store data, while a computer system may be used to perform data manipulations. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each

invention are different. Therefore, the inventions of Groups I, III, IV, VII and VIII are patentably distinct from each other.

B) Inventions I and (II, V, VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids may be used in a materially different method. The nucleic acids may be used for purification, isolation, hybridization assays, antisense methods or aptamer screening methods. Therefore, the nucleic acid product can be used in a materially different method.

C) Group (III, IV, VII, VIII) and II, V, VI are patentable distinct inventions because the peptides and antibodies of Groups III and IV is not relied upon in the method of Group II. Instead Group II, V, VI uses nucleic acids. Therefore, the inventions are novel and unobvious over one another.

D) The inventions of Group II, V, and VI are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group II is for measuring human expression. Alternatively, the method of Group V is for selling or licensing microarrays. Finally, Group VI is for providing data by subscription. Each of these groups rely on different reagents. For example, Group II uses nucleic acids. Groups V and VI use data in the

form of databases which are accessed for either sale or further data mining. Therefore the methods are distinct over one another.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper. The search required for each of the groups is not coextensive for any other group, such that a search of more than one group would place a burden on the examiner.

5. A telephone call was made to Roy Ronning on August 12, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is

(703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
Patent Examiner
August 12, 2003